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Docket No.: OSTEONICS 3.0-452 (PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:
Eric Jones

Application No.: 10/783,245 Group Art Unit: 3738

Filed: February 20, 2004 Examiner: Not Yet Assigned

For: SURFACE TREATMENT FOR A METAL PROSTHESIS

**CLAIM FOR PRIORITY AND SUBMISSION OF DOCUMENTS**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant hereby claims priority under 35 U.S.C. 119 based on the following prior foreign application filed in the following foreign country on the date indicated:

| Country | Application No. | Date |
|---|---|---|
| Great Britain | 0304168.8 | February 24, 2003 |

In support of this claim, a certified copy of the original foreign application is filed herewith.

Dated: June 10, 2004

Respectfully submitted,

By _____
Raymond W. Augustin
Registration No.: 28,588
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP
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I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: June 10, 2004 Signature: _____
(Raymond W. Augustin)

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

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Dated 24 February 2004

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*(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)*

The Patent Office

Cardiff Road
Newport
South Wales
NP9 1RH

1. Your reference

AJBB/SPY/H.114

2. Patent application number
*(The Patent Office will fill in this part)*

0304168.8

24 FEB 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

BENOIST GIRARD SAS

203, Boulevard de la Grande Delle - B.P.8.
14201 Hérouville-Saint-Clair Cédex
FRANCE

Patents ADP number *(if you know it)*

0809 833 7001

If the applicant is a corporate body, give the country/state of its incorporation

FRANCE

4. Title of the invention

SURFACE TREATMENT OF METAL

5. Name of your agent *(if you have one)*

G.F. REDFERN & CO.

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

7 Staple Inn,
Holborn,
London,
WC1V 7QF

Patents ADP number *(if you know it)*

1412002

08 42 535 6001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

| Country | Priority application number *(if you know it)* | Date of filing *(day / month / year)* |
|---|---|---|

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

| Number of earlier application | Date of filing *(day / month / year)* |
|---|---|

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

*a) any applicant named in part 3 is not an inventor, or*
*b) there is an inventor who is not named as an applicant, or*
*c) any named applicant is a corporate body.*
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YES

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

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| Continuation sheets of this form | |
| Description | 7 |
| Claim *(s)* | |
| Abstract | |
| Drawing *(s)* | 3 + 3 |

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| | |
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| Priority documents | |
| Translations of priority documents | |
| Statement of inventorship and right to grant of a patent *(Patents Form 7/77)* | |
| Request for preliminary examination and search *(Patents Form 9/77)* | |
| Request for substantive examination *(Patents Form 10/77)* | |
| Any other documents *(please specify)* | |

11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 24 February 2003

12. Name and daytime telephone number of person to contact in the United Kingdom

A.J. Bridge-Butler
020 7242 7680

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# SURFACE TREATMENT OF METAL

This invention relates to the surface treatment of metal and is more particularly, although not exclusively, applicable to the treatment of metal prostheses.

The insertion portions, for example stems, of prostheses such as hip implants stems are sometimes provided with a roughened surface to not only increase the grip of the stem in the bone but also encourage bone on-growth. Great concern is being expressed over the possible role that foreign body debris embedded in an implant surface, as a result of surface treatment, may have on the long-term functionality of prosthetic components. It has been shown that significant risks may be exposed that is directly linked to such contaminants.

US Patent No 5,456,723 describes a metal implant, which has a contact surface roughness of more than 20 microns to provide a good bond between the bone and the implant. This bond is significantly improved by giving the contact surface micro roughness of 2 microns or less. According to the invention this micro roughness is realised by treating a metallic body destined to become the implant with a reducing acid, which attacks the metallic surface to produce the specified micro roughness. This reducing acid may be one of a group of acids including hydrochloric acid, hydrofluoric acid, and a mixture of hydrochloric and sulphuric acids. The reducing acid is preferable made to exert its action on the implant in its boiling state. This acid treatment alone produced the results desired by effectively pitting the surface of the metal implant. Sandblasting may be used as a step preceding the reducing acid treatment.

According to the present invention a method of forming a roughened, decontaminated surface on a medical article includes the single or multiple blasting of the surface with a chilled iron grit of appropriate roughness structure (eg 180 –

1190 microns) and followed by acid pickling to produce a contamination free surface of substantially $S_q$ 6 microns.

Preferably the surface is pickled in nitric acid and in a preferred method the surface is pickled in 20% nitric acid for 40 minutes.

The use of nitric acid effectively dissolves the iron grit embedded or loosely held on the implant surface to provide a decontaminated surface.

Other dilute acids may be used that dissolve the iron grit, but do not attack the metallic implant.

Nitric acid is the preferred acid as it also passivates the surface of the metallic implant.

Ultrasonic agitation during the acid treatment process is preferable to loosen the partially solubilised iron salt from the surface of the metallic implant.

It has been found that the process is particularly applicable for use with a medical article made from titanium or titanium alloy.

The method may include blasting with G07 chilled iron grit at a pressure of 6.5 bar at 40 cubic metres per hour of air through a 9.5 mm nozzle and 4.8mm air jet.

The method can also include first blasting with G12 chilled iron grit at 105-psi air pressure through a 9 mm nozzle before blasting with the G07 grit.

The blasting time in both cases can be 3 to 4 minutes with a standoff distance between 25 – 50 mm

In any case, 3 cold-water rinses can be applied after pickling.

The method can be applied to a prosthesis, which has an insertion portion extending from an operative portion, the roughened decontaminated surface being formed on the insertion portion.

A protective cover can be applied to the operative portion and which is used to carry the prosthesis during blasting.

Grit selection is determined by the surface hardness of the material and, as mentioned above, for an un-machined (as forged) titanium alloy it is possible to use G 07 grit to obtain the required level of surface roughness.

For machined titanium alloy (the machining operation work hardens the titanium alloy surface) it is necessary, as stated above, to use two grits, a first blast with a G12 to give a rough, peaky surface and a second with G07 to cut the peaks down.

If the hardness is even greater it may be necessary to us an even rougher grade of grit to give the initial cut to the surface, and then refine to the desired surface profile with a less course grit.

The acid leach does reduce the roughness of the surface by a small amount. This is not, however, by attacking the surface of the alloy but by dissolving iron grit embedded in the titanium alloy surface, and which complements to the overall surface roughness.

The invention can be performed in various ways and one embodiment will now be described by way of example and with reference to the accompanying drawings in which:

Figure 1 is a pictorial view of a known preferred surface feature and table showing various parameters;

Figure 2 is a side elevation of a femoral prosthesis to which the method according to the present invention is applied; and

Figure 3 is a block diagram showing the method according to the present invention.

Some 20 years clinical history with a cementless, straight-stemmed hip has demonstrated that the typical preferred surface properties are: -

| | |
|---|---|
| $S_t$ | ten-point height of the surface is in the order of 50 microns |
| $S_{sk}$ | skewness of topography height distribution is in the order of zero |
| $S_q$ | root mean square deviation of the surface is in the order of 6 microns. |

An example of the preferred surface features is shown in Figure 1 and was measured by non-contacting surface profilometry that is a technique that is able to represent a pictorial display of the surface.

In the preferred surface profile, significant quantities of asperities protrude to give good initial interlock between the stem and the bone and thus imparting early post-operative stability. There is a balance of the valleys to cater for eventual bone on-growth, with the resultant skewness ($S_{sk}$) being close to zero.

The surface roughness is generally achieved by blasting the surface to be roughened with a blasting medium such as alumina particles.

In the method described the invention is applied to a prosthesis which has an insertion portion or stem that is to be inserted into a human bone and which extends from an operative portion. Figure 2 shows a femoral prosthesis to which the present

invention can be applied. The prosthesis comprises an insertion portion in the form of a stem 1 which extends from an operative portion provided by a neck 2 on which is a tapered spigot 3 to which a bearing ball can be fitted in known manner. The roughened decontaminated surface indicated by reference numeral 4 is formed on the stem 1.

The block diagram shown in Figure 3illustrates the process according to the invention. Prior to treating the titanium alloy prosthesis the operative portion 2 & 3 of the stem is either dipped or otherwise wrapped to provide a protective covering of polyurethane or other suitable material, which extends down the proximal end of the part of the stem to be treated and which is indicated by reference numeral 5. Thus, all the upper part of the prosthesis above the line 5 is covered by the protective coat, which is indicated by chain lines 6 in Figure 2. Prior to the protective coating, however, and as shown in Figure 3, the prosthesis is first degreased, for example, by using trichlorethane an indicated in Box 1. The protective coating is now applied as indicated in Box 2, and the prosthesis is now passed to blasting as indicated in Box 3. In the example being described a Guyson Multiblast six-station machine is used and the prostheses are held in position by clamps, which are attached to the protected portion provided by, for example, the polyurethane covering 6. As the prosthesis is made from machined titanium alloy its outer surface has hardened so, in the method being described the stem 1 is first blasted with G12 chilled iron grit for 3 minutes with a 9-mm nozzle at 105-psi air pressure.

The surface is then blow cleaned with air as indicated by Box 4 and is then blasted with G07 chilled iron grit, again for 3 minutes with a 9-mm nozzle at 105 psi air pressure as shown in Box 5. The surface is again blown clear by compressed air as shown in Box 6 and the prosthesis, as shown in Box 7 is placed in a bath containing 20% nitric acid for more than 30 minutes and less than 60 minutes with ultrasonic agitation.

The prosthesis is then rinsed in high pressure water as indicated in Box 8 and subsequently air blown dry (Box 9)

The specification of the chilled iron grit is shown below.

| C | Si | Co | Ni | Cr | Mo | S | P | Pb | Fe |
|---|---|---|---|---|---|---|---|---|---|
| 3.01 | 1.69 | 0.35 | 0.33 | 0.19 | 0.06 | 0.078 | 0.069 | 0.0016 | Bal |

Typical chilled iron grit sizes available for use are:

G07 (180 – 350 microns)

G07 sieved to remove the fraction above 300 microns

G05 (150 – 300 microns)

G12 (250 – 500 microns)

G34 (710 – 1190 microns)

Grit selection is determined by the surface hardness of the material for the desired surface roughness.

For un-machined (as forged) titanium alloy it is possible to use G07 grit only to obtain the required level of surface roughness and the stages shown in Boxes 3 and 4 will not be necessary.

For the machined titanium alloy (the machining operation work hardens the titanium alloy surface) as described above, it is necessary to use 2 grits.

A first blast with G12 gave a rough, peaky surface.

A second blast with G07 cut the peaks down.

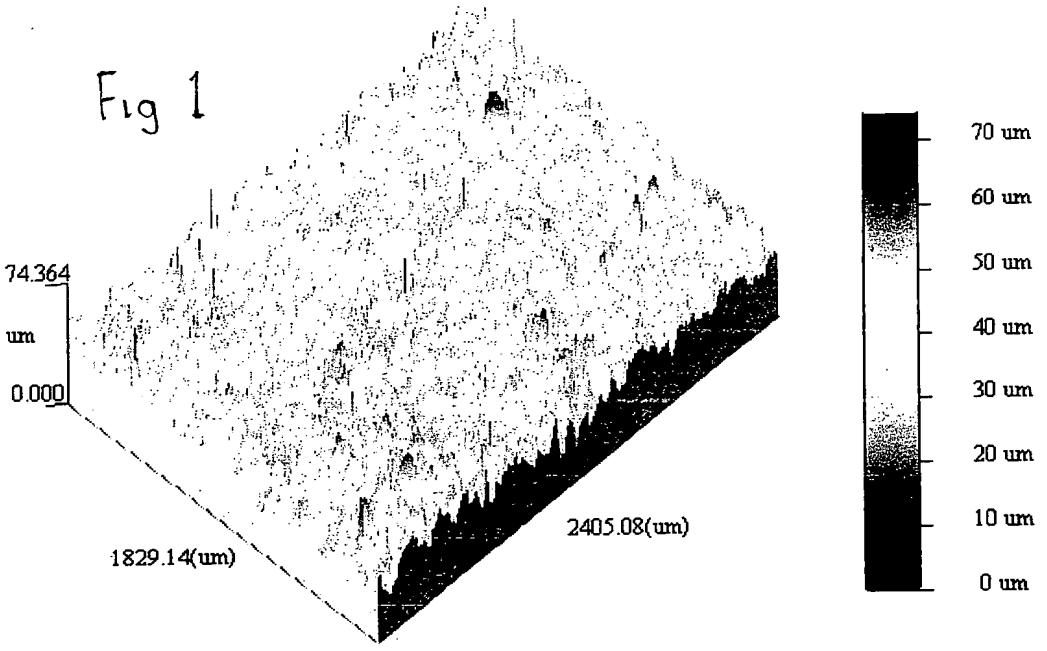
If the hardness is even greater, it may be necessary to use even rougher grit to give the initial cut into the surface.

The acid leach does reduce the roughness of the surface by a small amount. This is not, however, by attacking the surface of the alloy, but by dissolving the iron grit embedded in the titanium alloy surface.

The blasting time will depend upon the size of the implant and the metal, but is preferably between 3 to 4 minutes with a stand off distance of 25 – 50 mm.

It has been found (using EDAX probing for elemental analysis) that the surface is uncontaminated, the nitric acid acting to dissolve the residual iron grit, and this also provides a surface, which, depending upon the resting time can be $S_q$ 6 microns. (As determined using non-contacting surface profilometry.)

Fig 1




## AMPLITUDE PARAMETERS

| | | |
|---|---|---|
| *Root-mean-square deviation of the surface* | *Sq* ( μm ) | 6.742 |
| *Skewness of Topography height distribution* | *Ssk* | -0.324 |
| *Kurtosis of Topography height distribution* | *Sku* | 3.382 |
| *Highest Peak from the mean surface* | *Sp* ( μm ) | 34.506 |
| *Lowest Valley from the mean surface* | *Sv* ( μm ) | -39.858 |
| *Height between the lowest and highest points* | *Sz* ( μm ) | 74.364 |

## SPATIAL PARAMETERS

| | | |
|---|---|---|
| *Density of summits of the surface* | *Sds* ( 1/mm ) | 1.621e+003 |
| *Texture aspect ratio of the surface* | *Str* | 0.770 |
| *Fastest decay autocorrelation length* | *Sal* ( mm ) | 0.069 |
| *Texture direction of the surface* | *Std* ( degree ) | * |

## HYBRID PARAMETERS

| | | |
|---|---|---|
| *Root-mean-square slope of the surface* | *Sdq* | 0.775 |
| *Average summit curvature of the surface* | *Ssc* ( 1/μm ) | 0.261 |
| *Developed surface area ratio* | *Sdr* ( % ) | 20.366 |

## FUNCTIONAL PARAMETERS

| | | |
|---|---|---|
| *Surface bearing index (5%)* | *Sbi* | 0.279 |
| *Core fluid retention index (5-80%)* | *Sci* | 1.405 |
| *Valley fluid retention index (80%)* | *Svi* | 0.132 |
| *Peak material volume of the surface (10.0%)* | *Vmp* ( $\mu m^3/mm^2$ ) | 2.805e+005 |
| *Core material volume of the surface (10.0--80.0%)* | *Vmc* ( $\mu m^3/mm^2$ ) | 5.982e+006 |
| *Core void volume of the surface (10.0--80.0%)* | *Vvc* ( $\mu m^3/mm^2$ ) | 7.524e+006 |
| *Valley void volume of the surface (80.0%)* | *Vvv* ( $\mu m^3/mm^2$ ) | 8.860e+005 |

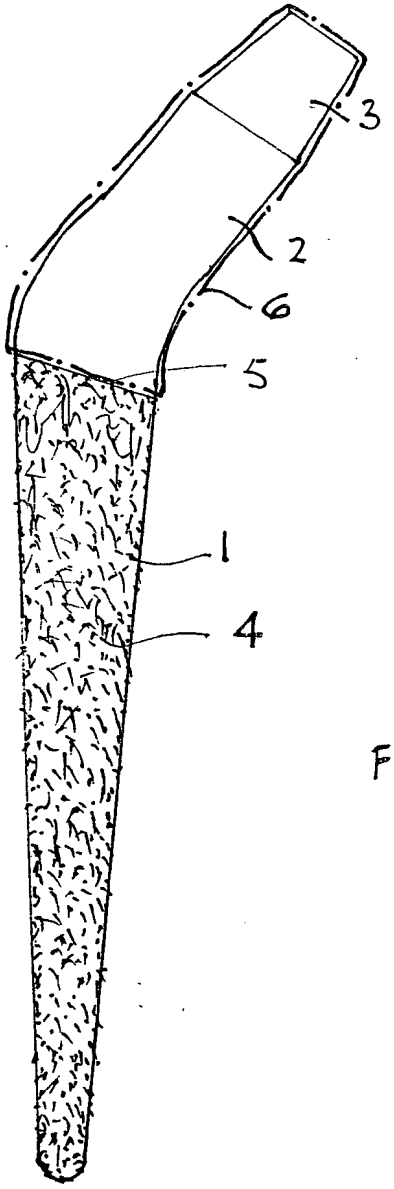



Fig 2

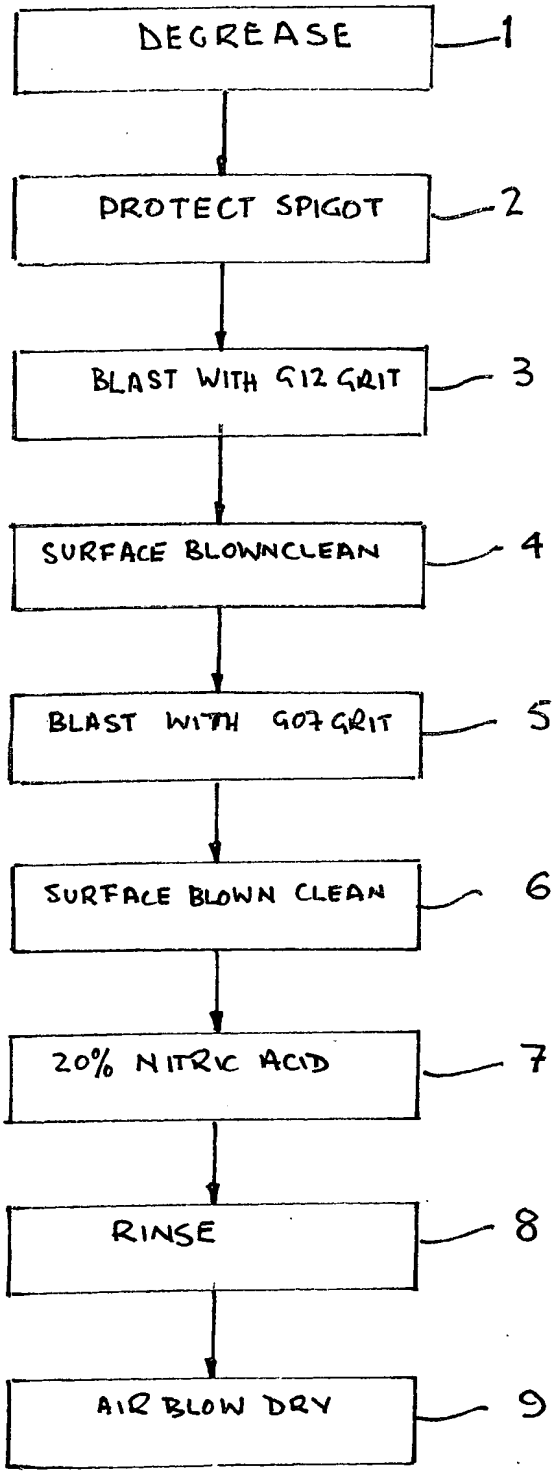

DEGREASE
1
PROTECT SPIGOT
2
BLAST WITH G12 GRIT
3
SURFACE BLOWNCLEAN
4
BLAST WITH G07 GRIT
5
SURFACE BLOWN CLEAN
6
20% NITRIC ACID
7
RINSE
8
AIR BLOW DRY
9

Fig 3